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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,877	07/27/2007	Indriati Pfeiffer	4007620-173752	2936

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PORTER WRIGHT MORRIS & ARTHUR, LLP  
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COLUMBUS, OH 43215

EXAMINER
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SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1633

NOTIFICATION DATE	DELIVERY MODE
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04/25/2012

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@porterwright.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/590,877	<b>Applicant(s)</b> PFEIFFER ET AL.	
	<b>Examiner</b> James D. (Doug) Schultz	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1, 5-11, 14-21 and 23-28 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1, 5-7, 9-11, 14, 16-21, and 23-27 is/are allowed.
- 7) ☒ Claim(s) 8, 15 and 28 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Status of Application/Amendment/Claims*

Applicant's response filed August 8, 2011 has been considered. Rejections and/or objections not reiterated from the previous office action mailed March 9, 2011 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Election/Restrictions*

Claims 1, 5-7, 9-11, 14, 16 and 17 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 18-21 and 23-27, directed to a process of making or using an allowable product, or to a combination that requires all the limitations of an allowed subcombination, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on May 4, 2010 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction

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requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on October 18, 2011 was filed before the mailing date of the instant first action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner, and a signed and initialed copy is enclosed herewith. The "Bjisterbock" reference has been struck through since it has been previously submitted and considered as noted in the IDS submitted 8/28/2006.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites "An oligonucleotide structure according to claim 7, wherein said third strand has a terminal hydrophobic anchoring moiety so first and third strands have adjacent hydrophobic anchoring moieties."

Claim 15 recites "An oligonucleotide structure according to claim 8, wherein the first strand has essentially double the amount of nucleic acid monomers then the second strand, and

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said first and second strands each have a cholesterol molecule attached to their free 5' and 3' ends, respectively.”

Both of these claims depend upon claim 1, which is drawn to an oligonucleotide having first and second strands, wherein the first strand and second strand have adjacent hydrophobic moieties, and wherein the opposing end of the first strand is free from a hydrophobic moiety. These limitations regarding terminal hydrophobic moieties on the first strand as recited in claims 1, 8, and 15 are mutually exclusive. For example, claim 8 requires that the first and second strands have adjacent hydrophobic anchoring moieties, which conflicts with the requirement of claim 1 that the first strand has a terminal hydrophobic moiety adjacent to a terminal hydrophobic moiety of the second strand, and that the opposing terminal of the first strand is free from a hydrophobic moiety. Similarly, claim 15 recites a first strand having cholesterol moieties at both terminal ends, while claim 1 from which it depends requires that the first strand have a terminal end free of a hydrophobic moiety. Resolution is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Tyagi et al. (WO 2002/33045, of record).

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Claim 28 is drawn to an oligonucleotide structure, comprising a first strand of nucleic acid and a second strand of nucleic acid, the first and second strands being hybridized to each other in a duplex section, and at least two hydrophobic anchoring moieties covalently attached to adjacent terminal ends of the first and second strands, respectively, and capable of attaching at adjacent sites on a lipid membrane, wherein a terminal end of the first strand is not part of the duplex section and is free from a hydrophobic moiety, and wherein the oligonucleotide structure is a linker available for binding to the lipid membrane.

Tyagi et al. teaches a duplexed oligonucleotide, wherein each oligonucleotide is covalently bound to a cholesterol moiety at their terminal ends which are adjacent to each other (see figure 4 for example).

#### Response to Applicants Traversal

Applicants traverse the instant rejection as applied to claim 28 by asserting that page 4, lines 12-14 of the specification defines "linker available for binding" as a linker that is capable of binding but is not yet bound. Applicants argue that the oligonucleotide of claim 28 is capable of binding to the lipid membrane but is not yet bound to the lipid membrane.

This argument has been fully considered but is not convincing. Applicant's characterization of the cited passage of the specification is incomplete at best. The reference to page 4, lines 12-14 of the specification actually recites: "As used herein, the term 'linker available for binding' refers to that a linker is adapted for binding, but the linker is not yet bound to another linker, or that all binding sites of the linker are not yet occupied." (Emphasis supplied). Clearly, the linker may be bound according to the underlined passage above, so long

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as all binding sites are not occupied. The structure of Tyagi has unoccupied binding sites, as evidenced by the fact that there are non-hybridized nucleotides in the oligonucleotide structure taught in figure 4 and elsewhere. Tyagi thus anticipates claim 28.

### ***Allowable Subject Matter***

Claims 1, 5-7, 9-11, 14, 16-21, and 23-27 are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. (Doug) Schultz whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/James D. (Doug) Schultz, PhD/  
Primary Examiner, Art Unit 1633